

REMARKS

Reconsideration of this application is respectfully requested.

Previously presented claims 1, 75-86, and 100 are pending in the application.

At the outset, Applicants gratefully acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Priority

The Office denied Applicants' claim for priority under 35 U.S.C. § 119(a)-(d), alleging that the instant application does not properly claim priority to U.S. Application No. 09/485,536 (Office Action at page 2.) Applicants submit that priority was claimed, as argued in the previous Reply. Applicants filed a PETITION FOR AN UNINTENTIONALLY DELAYED FOREIGN PRIORITY CLAIM UNDER 37 C.F.R. 1.55(c) on December 3, 2004, in which Applicants renewed this argument, and submitted in the alternative that any delay in claiming priority was unintentional.

Applicants submit that they have complied with the requirements for claiming priority to PCT/FR98/01813, FR 97/10,404, and FR 97/11,325. Applicants have amended the first paragraph of the specification herein to include a reference to the priority that was claimed.² No new matter is introduced by this amendment.

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 75, 76, 79, 81-84, and 100 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gicquel et al., FR 2 767 336 ("FR '336"). The publication date of FR 2 767 336 is February 19, 1999. This is *after* the international filing date of

² This amendment was also included in the previous Reply. Because it was not entered Applicants resubmit it here.

PCT/FR98/01813, which is the filing date of the '536 application, to which the instant application claims priority under 35 U.S.C. § 120. Under § 363 this international filing date is the filing date of the '563 application, and under § 120 it is the effective filing date of the instant application.. Thus, FR '336 is not prior art to the instant application. In view of these circumstances, Applicants ask that the Examiner withdraw the rejection for anticipation over FR '336.

Applicants also note that the only ground of rejection applied against claims 80 and 85 was for an alleged anticipation over FR '336. As FR '336 is not prior art against the instant application, Applicants respectfully submit that claims 80 and 85 are allowable.

Claims 1, 75, 76, 79, 81-84 and 100 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by either Gicquel et al. (US 6,248,581 B1) ("the '581 patent") or Gicquel et al. (WO 96/07745) ("WO '745"). As described above, the effective United States filing date of the instant application is the August 14, 1998, filing date of PCT/FR98/01813. Thus, the '581 patent is not prior art under 35 U.S.C. § 102(b) to the instant application. In view of these circumstances, Applicants ask that the Examiner withdraw the rejection for anticipation over the '581 patent.

The pending claims are not anticipated by WO '745. The invention of the present claims generally provides a way to identify mycobacterium sequences coding for polypeptides, which are exported and/or secreted and, which can be induced or repressed during infection (Application at page 8, lines 16-24 and 27-32; page 12, lines 14-20; and page 15, lines 9-15). The identification of these sequences provides a basis for selecting good candidate vaccines and for understanding the interaction between

mycobacteria and their host cells (see application at page 7, lines 27-33). In order to identify such mycobacteria sequences, the inventors have constructed a recombinant vector comprising both a sequence coding for an export and/or secretion marker and a sequence coding for a marker for the activity of promoters, this second sequence being inserted with its initiation codon in order to be expressed along with the export and/or secretion sequence, such as a synthetic operon (see Application at page 73, lines 1-3). For example, in Example 2 of the application, the polypeptide DP 428 is shown to be strongly induced during *Mycobacterium* phagocytosis when using recombinant *Mycobacterium tuberculosis* transformed by the recombinant vector “pJVED” of the present invention.

Thus, the rejected claims recite a “vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, **and d)** a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” (Emphasis added.)

In contrast to the invention of the rejected claims, WO ‘745 generally concerns the identification of Mycobacterial sequences coding for polypeptides, which are exported and/or secreted (see Example I), or the evaluation of different expression promoters in Mycobacteria (see Example III). As shown in these Examples I and III, the identification of these exported and/or secreted sequences or of these expression

promoters is carried out in isolated mycobacteria and not in a “Mycobacterial context” (that it to say in presence of macrophages).

As pointed out by Applicants in their previous Reply, none of the **vectors** in WO ‘745 contain a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, where the nucleotide sequence lacks its initiation codon and its regulatory sequences (element (3)(c) of claim 1), **and** a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, and where the nucleotide sequence has its initiation codon (element (3)(d) of claim 1). Instead, the vectors of WO ‘745 comprise a sequence lacking its initiation codon, coding for an export and/or secretion marker, such as truncated phoA (see vector pJEM 11 in Example I); **or** a sequence lacking its initiation codon coding for a marker of activity of promoter, such as truncated LacZ (see vectors pJEM 12, 13 and 14 in Example III). Because of this deficiency, WO ‘745 fails to disclose every element of the claimed invention and can not anticipate the rejected claims for this reason. *See Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.”); M.P.E.P. § 2131.

In the outstanding Office Action, the Examiner replied to Applicants’ previous Reply by pointing to the abstract of WO ‘745 and stating that “WO ‘745 does teach a marker,” citing the abstract of WO ‘745 in support of this contention. (Office Action at page 5.) Applicants respectfully submit, however, that the abstract of WO ‘745 describes a vector that does not include element (3)(d) of Applicants’ claim 1. The

Examiner appears to attempt to explain this distinction away, by noting that the vector described in the abstract of WO '745 includes a selection marker, and further noting that a selection marker must be linked to a promoter to be expressed. Applicants submit that this statement overlooks all elements of their claims, however.

Specifically, Applicants' claims recite a selectable marker (as element (2)), which is distinct from the reporter cassette (element 3). Thus, sub-elements (a-d) within element 3 of Applicants' claims are present in the claimed vector in addition to element (2). Assuming, for the sake of argument only, that WO '745 does describe a vector comprising a selectable marker as in element (2) of Applicants' claims, WO '745 does not describe a vector that further includes a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, where the nucleotide sequence lacks its initiation codon and its regulatory sequences (element (3)(c) of claim 1), **and** a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, and where the nucleotide sequence has its initiation codon (element (3)(d) of claim 1). This is so even if the selectable marker of the vector in WO '745 inherently includes a promoter, as suggested by the Examiner (which Applicants do not admit).

For the above reasons, Applicants submit that WO '745 does not disclose all elements of the rejected claims and can not anticipate the rejected claims for this reason. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection for anticipation over WO '745.

Double Patenting

Claims 1, 75, 76, and 79 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 5 and 6 of U.S. Patent No. 6,248,581. (Office Action at pages 3-5.) According to the Office, “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 79 are generic to the expression vector recited in claims 5 and 6 of U.S. Patent No. 6,248,581.” (Office Action at pages 3-5.) Applicants respectfully traverse.

Claim 1, and claims 75, 76, and 79 as they depend from claim 1, recite a “vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, **and** d) a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” (Emphasis added.) This combination of elements is not present in claims 5 and 6 of U.S. Patent No. 6,248,581, for the same reasons provided above for why this combination of elements is not present in WO ‘745. Accordingly, contrary to the Office’s assertion, claims 1 and 79 are not generic to claims 5 and 6 of U.S. Patent No. 6,248,581.

When, as here, the Office asserts that a claim in an application is an obvious variant of a claim in an issued patent, and the pending application was filed after the application that matured into the patent, the issue is whether the invention defined in a claim of the application is an obvious variation of the invention defined in a claim of the

issued patent. M.P.E.P. 804(II)(B)(1). Obviousness in this context is assessed based on a one-way test, considering the pending claims in view of the issued claims. M.P.E.P. 804(II)(B)(1). The remaining disclosure of the patent may not be used as prior art. M.P.E.P. 804(II)(B)(1). An obviousness-type double patenting rejection is analogous to a rejection under 35 U.S.C. § 103(a), and the elements of the analysis are the same. *See* M.P.E.P. 804(II)(B)(1).

Neither claims 5 nor 6 of the '581 patent recite a “vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, **and d)** a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” Applicants submit that this combination of elements is not present in the '581 patent claims, and that nothing in the prior art would have suggested or motivated one skilled in the art to modify the '581 patent claims to arrive at the invention defined by Applicants’ pending claims, which all require this combination of elements. Indeed, the Office has not pointed to any such disclosure, suggestion, or motivation, and, likewise, has not even provided any rationale of its own as to how such a disclosure, suggestion, or motivation could arise.

For this reason, claims 1, 75, 76, and 79 are nonobvious over claims 5 and 6 of the '581 patent, and an obviousness-type double patenting rejection is inappropriate. Accordingly, Applicants request that the Examiner withdraw the rejection for obviousness-type double patenting.

Conclusion

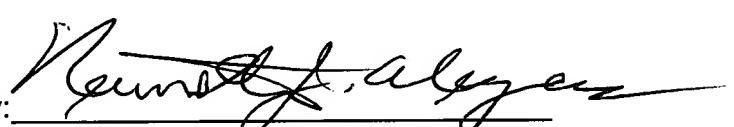
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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